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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,206	06/13/2000	RONG FU WANG	2026-4269US1	1577

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/529,206	WANG ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-8,10,12-15,26,28,29,67-77,83-85 and 87-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-8,10,12-15,26,28,29,67-77,83-85 and 87-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 July 2005 has been entered.

2. Claims 1-2, 4, 9, 11, 16-25, 27, 30-66, 78-82 and 86 have been cancelled.

Claims 3 and 26 have been amended.

3. Claims 3, 5-8, 10, 12-15, 26, 28-29, 67-77, 83-85 and 87-103 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

6. The rejection of claims 3, 5-8, 10, 12-15, 26, 67-77 and 87 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "functionally equivalent variant" is withdrawn in view of the amendments to the claims.

7. The rejection of claims 3, 5-8, 26, 67-68 and 87 under 35 U.S.C 112, first paragraph, as the specification does not contain a written description of the claimed

invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is withdrawn in view of the new grounds of rejection below.

8. The rejection of claims 3, 5-8, 10, 12, 26, 67-69, 72, 87-88 and 92-103 under 35 U.S.C 112, first paragraph, for introducing NEW MATTER, is withdrawn in view of applicants arguments and amendments to the claims.

9. The rejection of claims 28-29 and 83-85 under 35 U.S.C. 102(a) as being anticipated by Chen et al is withdrawn in view of the amendments to the claims.

Response to Arguments

10. The rejection of claims 3, 5-10, 12-15, 26, 28-29, 67-85 and 87-103 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention is maintained and made again.

The response filed 7/15/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that a reasonable expectation of success in not required to demonstrate enablement, rather it is one of the criteria for a prima facie case of obviousness and applicant reiterates that the level of skilled artisan as evident by the art of Gill et al and Estaquier et al is sufficient to make and use the full scope of the instant invention. In response to these arguments, the claims remain broadly drawn to a substantial number of variant cancer peptide sequences and the specification does

not provide sufficient guidance or direction to assist the skilled artisan in making and using the encompassed variant cancer peptides commensurate in scope with the claims. The specification does not teach any variant cancer peptide that contains an additional 1 to about 10 or 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the cancer peptide consisting amino acids 127-136 of SEQ ID NO:4 wherein the variant cancer peptide stimulates cytotoxic T lymphocytes or more specifically, stimulates HLA-A31, HLA-A3, HLA-A11, HLA-A33 and HLA-A68 MHC class I restricted cytotoxic T lymphocytes or wherein the cancer peptides are derived from the myriad of cancers encompassed by claims 7 and 96. The specification only teaches the cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4 (i.e., SEQ ID NO:15) (see Table 6) and stimulates cytotoxic T lymphocytes in vitro. The specification provides no guidance or direction assisting the skilled artisan in selecting cancer peptide variants that optionally have 1 to about 5 or 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4 nor does the specification teach the MHC restriction of the cancer peptide variants or the expression of SEQ ID NO:4 to assist the skilled artisan in deriving the claimed cancer peptides from the full scope of cancers recited in claims 7 and 96. Further, it is unclear if the additional contiguous amino acids are the N-terminal contiguous amino acids to amino acids 127-136 of SEQ ID NO:4 or if the contiguous amino acids are selected from just any contiguous sequence of SEQ ID NO:4. Similarly, the full scope of the cancer peptide variants consisting of amino acids 55-62 of SEQ ID NO:4 are not enabled in view of the limited disclosure of the cancer

peptide variants that stimulate cytotoxic T lymphocytes, the lack of teachings pertaining to MHC class I restriction of said cancer peptide variants and the lack of NY-ESO-1 tumor antigen (SEQ ID NO:4) expression data in the presently claimed cancers from which the cancer peptide variants are to be derived.

The art of Estaquier et al and Gill et al cited by applicant does not provide adequate evidence to support the full scope of the presently claimed cancer peptide variants. The art of Gill et al is directed towards the antigenicity of synthetic peptides and the factors that influence their ability to elicit antibodies, whereas the presently claimed invention is drawn to cancer peptides in terms of MHC restriction and stimulation of cytotoxic T lymphocytes. The art of Estaquier et al (abstract only) is directed towards a combinatorial library of peptides (i.e., "mixotope") and confirms that additional experimentation would have to be carried out to discover those peptides that stimulate cancer antigen specific cytotoxic T lymphocytes. The art of Estaquier et al does not provide any guidance or direction with respect to MHC restriction or the ability of antigen specific stimulated cytotoxic T lymphocytes to faithfully mimic the naturally processed antigen or whether the synthetic cancer peptide variants will effectively stimulate cytotoxic T lymphocytes that recognize tumor cells naturally expressing NY-ESO-1 (i.e., SEQ ID NO:4) in vivo. It is acknowledged that a reasonable expectation of success is a criteria for a prima facie case of obviousness, however, as pointed out at page 13 of the Applicant's response filed 5/10/2005, "The level of predictability in the art" is one of the Wands factors considered for enablement. Given the unpredictability in the art as it pertains to the claimed cancer peptide variants and the ability to stimulate

cytotoxic T lymphocytes (e.g., Table 7 of the specification), one of skill in the art would not have a reasonable expectation of success in producing and using the full scope of cancer peptide variants. The art recognizes that synthetic cancer peptides that effectively stimulate cytotoxic T lymphocytes and provide tumor protection is unpredictable. The art of Le Gal et al (Journal of Immunotherapy, 28(3):252-257, May/June 2005), indicates that the TCR features of natural and vaccine-induced NY-ESO-1-specific cytotoxic T lymphocytes are distinct and suggest that synthetic peptides used for vaccination may fail to faithfully mimic the naturally processed antigen (see entire document). Khong et al (Journal of Immunotherapy, 27(6):472-477, Nov/Dec 2004) teach that vaccination with an HLA-A2-restricted peptide of NY-ESO-1 generated primarily T cells that did not recognize tumor after in vitro sensitization and "This raises questions about the use of synthetic peptides derived from NY-ESO-1 as a sole form of immunization." (see abstract). Additionally, the art of Gnjatic et al (Proc. Natl. Acad. Sci. USA, 99(18):11813-11818, 2002) further exemplifies the unpredictable nature of the presently claimed invention. Gnjatic et al teach that for NY-ESO-1 peptide 157-165 (S9C) and NY-ESO-1 cancer peptide 159-167 (L9L), reactivities are mutually exclusive, CD8+ T cells recognizing these peptides do not cross-react and L9L-specific CD8+ T cells failed to recognize tumor cells naturally expressing NY-ESO-1 or B lymphoblastoid cells transduced with NY-ESO-1. Further, the NY-ESO-1 cancer peptide 157-167 (S11L), which differs from S9C by two additional amino acids at the C-terminus, stimulates a specific response that is distinct from S9C (see results section at page 11815). Thus, even minor changes in the structure of the NY-ESO-1 cancer peptide

can alter the reactivities and stimulated cancer specific cytotoxic T lymphocytes may fail to recognize tumor cell naturally expressing NY-ESO-1. Additionally, as pointed out in the previous Office Actions, Table 7 evinces that that not all cancer peptide variants embraced by the claims will have the requisite cytotoxic T lymphocyte activity. The cancer peptide consisting of amino acids 54-62 of SEQ ID NO:4 recited in claims 13 and 88 does not stimulate cytotoxic T lymphocytes (see Table 7; SEQ ID NO:31) and one skilled in the art would not know how to use a cancer peptide for stimulating cytotoxic T lymphocytes that does not work. Further, the cancer peptides consisting of amino acids 48-62 and 43-62 recited in claims 14-15 and 88 are not disclosed as stimulating cytotoxic T lymphocytes. Thus, without further guidance and direction in applicant's specification, one skilled in the art could not predictably produce and use the full scope of the cancer peptide variants encompassed by the broad scope of the claims without undue experimentation.

A patent is not a reward for a search, but compensation for its successful conclusion. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Applicant's arguments are not persuasive because as discussed above they are merely an invitation to the skilled artisan to experiment using the specification as a guide to determine for themselves which cancer peptide variants will work.

In view of the unpredictability of the art to which the invention pertains, the lack of established clinical protocols for effective cancer therapies, undue experimentation would be required to practice the full scope of the claimed NY-ESO-1 cancer peptides

with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed NY-ESO-1 cancer peptides and absent working examples providing evidence which are reasonably predictive that the claimed NY-ESO-1 cancer peptides effectively stimulate cytotoxic T lymphocytes for cancer therapy, commensurate in scope with the claimed invention.

New Grounds of Objections/Rejections

11. The disclosure is objected to because the specification discloses the term "MHLA-A31" (see page 33, line 3) and "MHL-A31" (see page 33, line 14) and the term "MHL-A31" at page 51, line 3. Which spelling is correct or do the terms have different meanings? Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

12. Claims 13, 72 and 87 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 13 does not further limit base claim 3 because claim 13 recites a cancer peptide that is one amino acid shorter (i.e., amino acids 54-62 of SEQ ID NO:4) than the cancer peptide "consisting of amino acids 53-62" and as such does not incorporate all of the limitations of the base claim from which it depends and does not further limit the cancer peptide

consisting of amino acids 53-62 of SEQ ID NO:4. Additionally, claim 72 recites that the cancer peptide consists of amino acids 54-62 and an additional amino acid at the N-terminus of the cancer peptide, which does not further limit base claim 3, which requires that the cancer peptide consist of amino acids 53-62 of SEQ ID NO:4 wherein the N-terminal amino acid is alanine. Thus, claim 72 which encompasses any amino acid at position 53 of the cancer peptide does not further limit the scope of the cancer peptide consisting of amino acids 53-62 of SEQ ID NO:4.

Claim 87 does not further limit the cancer peptide of base claim 3, which requires that the cancer peptide minimally consist of 10 amino acids (i.e., amino acids 53-62 or 127-136 of SEQ ID NO:4), however, claim 87 recites that the cancer peptide is "about 10 amino acids in length", which embraces cancer peptides that are less than 10 amino acids in length and as such do not further limit the cancer peptide consisting of amino acids 53-62 or 127-136 of SEQ ID NO:4.

13. Claims 7 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 96 are indefinite for reciting "derived" as the exact meaning of the word is not known. The term "derived" is not one, which has a universally accepted meaning in the art nor is it one, which has been adequately defined in the specification. The primary deficiency in the use of this term is the absence of an ascertainable meaning for said term. Since the nature, extent and direction of the derivatization to

yield the class of derivatives referred to in the claims is unclear, there is no way for a person of skill in the art to ascribe a discrete and identifiable class of compounds to said phrase. In addition, since the term "derived" does not appear to be clearly defined in the specification, and the term can encompass peptides with amino acid substitutions, insertions, deletions, chemically derivatized peptides, or even mimetics. In absence of a single defined art recognized meaning for the phrase and lacking a definition of the term in the specification, one of skill in the art could not determine the metes and bounds of the claims.

14. Claims 3, 5-8, 12, 26, 28-29, 67-69, 72, 83-85, 87-88 and 92-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated isolated cancer peptides consisting of amino acids 53-62 of SEQ ID NO:4 or functionally equivalent variants thereof having at least 90% sequence identity with amino acids 53-62 of SEQ ID NO:4 and wherein the cancer peptides optionally contain about 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the cancer peptide consisting of amino acids 53-62 of SEQ ID NO:4 or wherein 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 are present at the N-terminus of the cancer peptide consisting of amino acids 53-

62 of SEQ ID NO:4. Additionally the claims are drawn to an isolated cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4 and optionally containing 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4 or wherein 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 are present at the N-terminus of the cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4. Further, the claims are drawn to compositions comprising an isolated cancer peptide as discussed above.

The specification discloses the cancer peptides consisting of amino acids 53-62 of SEQ ID NO:4 (SEQ ID NO:25; Table 7) and consisting of amino acids 127-136 of SEQ ID NO:4 (SEQ ID NO:15; Table 6), which stimulate cytotoxic T lymphocytes. The specification does not disclose or provide adequate written description of the genus of isolated cancer peptides consisting of amino acids 53-62 or 127-136 of SEQ ID NO:4 and containing an additional contiguous amino acids (1 to about 5 and 1 to about 10) at the N-terminus of the isolated cancer peptide that stimulates cytotoxic T lymphocytes or MHC I restricted cytotoxic T lymphocytes selected from HLA-A31, HLA-A3, HLA-A11, HLA-A33 and HLA-A68. The species of cancer peptides disclosed in Table 7 are insufficient to constitute a representative number of species that constitute the genus because the genus is highly variable and one of skill in the art could not predict the operability in the invention of any species other than the one's disclosed.

A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species

to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. " See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.).

It has been well known that minor structural differences even among structurally related compounds can result in substantially different biology, expression and activities. Based on the instant disclosure one of skill in the art would not know which sequences are essential, which sequences are non-essential and what particular additional sequence and sequence lengths are to be added to the N-terminus of recited cancer peptides (i.e., SEQ ID NO;25 and SEQ ID NO:15) wherein the resultant cancer

peptides stimulate MHC class I restricted cytotoxic T lymphocytes. For example, there is insufficient guidance based on the reliance of disclosure of the cancer peptide consisting of amino acids 127-136 of SEQ ID NO:4 and amino acids 53-62 of SEQ ID NO:4 that stimulate HLA-A31 restricted cytotoxic T lymphocytes to direct a person of skill in the art to select or to predict particular sequences as essential for identifying cancer peptides that are 90% identical to amino acids 53-62 of SEQ ID NO:4 and the cancer peptides of SEQ ID Nos:25 and 15 having additional sequence at the N-terminus that stimulate MHC class I restricted cytotoxic T lymphocytes encompassed by the claims. Mere idea of function is insufficient for written description; isolation and characterization at a minimum are required.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al, Journal of Cell Biology, 111:2129-2138, November 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with asparagine, did not affect biological activity while the replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (see Lazar et al Molecular and Cellular Biology, 8(3):1247-1252, March 1988). Further, NY-ESO-1 peptide 157-165 (S9C) and NY-ESO-1 peptide 159-167 (L9L) reactivities are mutually exclusive, CD8+ T cells recognizing these peptides do not cross-react (see Gnjatic et al, Proc. Natl. Acad. Sci., USA 99(18):11813-11818, 2002; particularly Figs. 4-5 and Table 4). Further, the NY-

ESO-1 cancer peptide 157-167 (S11L), which differs from S9C by two additional amino acids at the C-terminus, stimulates a specific response that is distinct from S9C (see results section at page 11815). For example, patient NW86, was vaccinated with peptides S9C and S11L and failed to respond to S9C (see page 11815, right column). Further, Table 7 of the specification further exemplifies the unpredictability within the genus of cancer peptides presently claimed. Thus, the skilled artisan could not predict the operability in the invention of any species of cancer peptides having 90% sequence identity with amino acids 53-62 of SEQ ID NO:4 or cancer peptides consisting of amino acids 53-62 or 126-137 of SEQ ID NO:4 and optionally containing 1 to about 5 or 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of said cancer peptides.

In the absence of sufficient guidance and direction to the structural and functional analysis, applicant's reliance on the cytotoxic T lymphocyte activity of certain species of cancer peptides (i.e., Tables 6-7) does not provide sufficient written description for the genus of cancer peptides and functionally equivalent variants encompassed by the claimed cytotoxic T lymphocyte specificities in view of the above evidence, which indicates ordinary artisans could not predict the operability in the invention of any species other than the one's disclosed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of cancer peptide variants, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddles v.Baird*, 30 USPQ2d 1481, 1483. In *Fiddles v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only isolated cancer peptides consisting of amino acids 127-136 of SEQ ID NO:4 and consisting of amino acids 53-62 and the variants thereof that stimulate HLA-A31 restricted cytotoxic T lymphocytes (Table 7), but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Applicant's response filed 7/15/2005 has been carefully considered, but is deemed not to be persuasive. Applicant's arguments with respect to homologous

sequences of SEQ ID NO:4 are moot in view of the new grounds of rejection set forth above. The response also argues that a representative number of species of the claimed genus is provided by the originally filed specification, disclosed in Tables 6 and 7 where at least 14 examples of the claimed cancer peptides are presented. In response to this argument and as set forth above, the description of a limited number of species does not adequately describe the genus because of the unpredictability in the results obtained from species other than those specifically enumerated.

Conclusions

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER